Indian Health Service

Division of Diabetes Treatment and Prevention

Leading the effort to treat and prevent diabetes in American Indians and Alaska Natives

Recommendation for the Use of A1C for the Diagnosis of Diabetes and Pre-diabetes

in the Indian Health System

HbA1c (A1C) is a straight-forward test to evaluate a patient for the presence of diabetes and/or pre-diabetes that can be administered whenever patients encounter the health care system. Up until now we have had only tests that require the patient to be fasting and these often reduced the opportunities for testing. Many providers have expressed the desire to use the A1C test, hoping to overcome the logistical issues of the oral glucose tolerance test (OGTT) and the fasting plasma glucose (FPG), as well as to have a test which reflects overall recent glycemia as opposed to tests that reflect only one point in time.

In 2009, the American Diabetes Association (ADA), the European Association for the Study of Diabetes, and the International Diabetes Federation commissioned an International Expert Committee to evaluate this issue. The committee published its report in the July 2009 issue of the journal *Diabetes Care*. The committee recommended not only that A1C should become a diagnostic test for diabetes but that it should become the ***preferred*** diagnostic test for diabetes. After considerable scientific debate, ADA then officially added A1C to its list of diagnostic tests in its 2010 Clinical Practice Recommendations. This step has come as the result of clear evidence that A1C correlates well with FPG and OGTT results. Over the past decade there has been a nationwide initiative to improve standardization of the A1C assay which has made the test more accurate and reproducible across laboratories. Of particular significance to Indian Health populations is that the accuracy of using A1C has been demonstrated in data from longitudinal research among Pima Indians.

The purpose of this statement is to inform Indian Health clinicians about this significant change as well as to ***make the recommendation that A1C become the preferred test for diagnosing diabetes and pre-diabetes in non-pregnant patients in our populations.***

1. **Diagnostic criteria for diabetes and pre-diabetes:**
    a. A1C ≥6.5% (pre-diabetes = A1C 5.7-6.4%) **OR**
    b. FPG ≥126 mg/dL (pre-diabetes = 100-125 mg/dL or impaired fasting glucose - IFG) **OR**
    c. 2 hour OGTT ≥200 mg/dL (pre-diabetes = 140-199 mg/dL or impaired glucose tolerance - IGT) **OR**
    d. Random plasma glucose ≥200 mg/dL with symptoms of hyperglycemia
    e. Why now?
        - A1C assay has been standardized across the country, and
        - Research shows that A1C works for diagnosis at these values.

2. **A1C is the recommended test for general clinical purposes in the Indian Health System:**
    a. Why?
        - No fasting required (as with FPG)
        - No timed testing or administering glucose load (as with OGTT)
        - Reflects overall glycemia, not just one point in time
        - A1C test validated with data from our population: Pima Indians
        - Recommended as preferred test by the International Expert Committee
        - Can still use other tests for diagnosis if clinical circumstances dictate
            - though use of OGTT is rarely needed outside of pregnancy

3. **How to use A1C for diagnosis:**
    a. Ensure that A1C is clearly and accurately listed in EHR or other local medical record.

b. Can screen with a point of care (POC) A1C test, however ADA recommends that laboratory-run tests be used to diagnose diabetes.
c. If A1C test is ≥6.5%, repeat A1C test to confirm.
    - Why? To rule out lab error
d. If get two tests (e.g. A1C and FPG) and one is in the diagnostic range and the other isn't, what do you do?
    - Repeat the test which was in the diagnostic range and base the diagnostic decision on the basis of the confirmed test.
e. If get two tests (e.g. A1C and FPG) and both are significantly elevated, don't necessarily have to confirm with repeat test of either if fits the clinical picture.

4. When not to use A1C for diagnosis:

a. Hemoglobinopathies—HbS, HbC, HbF, HbE may interfere with some A1C assays.
b. Variation in red blood cell lifespan (e.g. hemolysis, blood loss, blood transfusions).

5. Glycemia and risk for progression to diabetes:

a. Glycemia risk is a continuous variable:
    - Diabetes risk increases as blood sugars increase.
    - There is no lower glycemic threshold at which risk clearly begins.
b. Glycemia is not the only marker of increased risk of progression to diabetes:
    - Adding other metabolic markers gives more complete picture of risk:
        - BMI / waist circumference
        - Hypertension
        - Dyslipidemia

6. Testing for diabetes/pre-diabetes in non-pregnant asymptomatic AI/AN individuals

a. Adults: overweight/obese (BMI ≥25) and/or strong family history of type 2 diabetes in 1st or 2nd degree relative and/or history of gestational diabetes (GDM).
b. Children: >10 years of age (or earlier if have entered puberty)
    - if BMI >85th %ile and any of the following:
        - Family history of type 2 diabetes in 1st or 2nd degree relative, **OR**
        - Presence of a condition associated with insulin resistance [*Acanthosis nigricans*, Hypertension, Dyslipidemia, Polycycstic Ovarian Syndrome (PCOS)], **OR**
        - Maternal history of pre-existing or gestational diabetes during child's gestation.

7. Using A1C for diagnosis will likely increase numbers of patients diagnosed with diabetes and pre-diabetes:

a. Sites should have a plan for how to provide appropriate care to these patients.
    - Early diabetes detection with aggressive blood glucose control has been shown to improve long-term disease course.
b. Programs to prevent diabetes for those with pre-diabetes should become high priority.

References:

1. American Diabetes Association. 2010. Clinical Practice Recommendations 2010. *Diabetes Care* 33 (Supplement 1).
2. International Expert Committee Report on the Role of the A1C Assay in the Diagnosis of Diabetes. 2009. *Diabetes Care* 32(7):1327-1334.
3. Gong Q, Hanson RL, Mason CC, Knowler WC. 2009. HbA1c in the Diagnosis and Prediction of Diabetes. ADA 69th Scientific Sessions Poster.